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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,574	11/12/2002	Dietmar Becher	07038-0004UI	6881

23859 7590 03/24/2004

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,574

Applicant(s)

BECHER ET AL.

Examiner

Konstantina Katcheves

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 17,18 and 20 is/are allowed.
- 6) ☒ Claim(s) 1-3,7-16,19 and 21-23 is/are rejected.
- 7) ☒ Claim(s) 4-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/8/2002.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending in the present application.

Drawings

The drawings are objected to because figure 7 contains text which recites the term “fig 2”. This inconsistency requires correction. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 6 is objected to because of the following informalities: Claim 6 contains a typographical error. The first three letters of the accession number are missing. The accession number should apparently read “DSM 12920.” Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: On page 5 of the specification, no dates of deposit have been provided. See 37 CFR 1.809(d)(2). Additionally, the address for the depository is wrong. The city name is Braunschweig not Brunswick. See MPEP 2405 and www.dsmz.de.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 is drawn to “a DNA sequence including” SEQ ID NO:1. SEQ ID NO:1 is derived from *Kluyveromyces marxianus*. Claims drawn to DNA read on genomic DNA which is a product of nature and thus not statutory subject matter according to 35 U.S.C. 101. See also MPEP 706.03(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 8-11, 13, 14, 15, 16, 21 and 23 rejected under 35 U.S.C. 102(b) as being anticipated by Siekstele et al. (Yeast Vol.15 no.4 1999).

The invention of the instant claim is drawn to an expression vector comprising a nucleotide sequence of SEQ ID NO:1, or a part thereof, a nucleotide sequence of SEQ ID NO:2, or a part thereof, and a nucleotide sequence of SEQ ID NO:3 and an insertion cloning site. The invention further comprises a foreign protein or peptide. The vector of the present claims is episomal and expressible in yeast. The invention further comprises a method for expressing a foreign protein or peptide by transforming a host cell with the claim expression vector.

Art Unit: 1636

Siekstele et al. disclose an episomal expression vector comprising a polynucleotide encoding the protein, EPG1 of *Kluyveromyces marxianus*, including a cloning site, terminator and an encoded signal sequence found between the promoter and the sequence encoding the EPG protein, plasmid pKEPEC. See page 318, figure 4. The construct also comprises a part of the promoter or SEQ ID NO:1 including the TATA box, CAAT boxes and CT block. See page 316, positions -513 to -1 of the figure depicted in figure 2 and Accession number AJ000076. The construct comprises the signal sequence of SEQ ID NO:3 in addition to the terminator of SEQ ID NO:2 in the construct pKEPEC. See page 316, positions 1 to 75 and approximately positions 1146 to 1648 of figure 2 and Accession number AJ000076. Siekstele et al. further disclose *K. marxianus* hosts with pKEPEC wherein the proteins encoded were expressed. See page 318, column 2.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 8-16, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The invention of the present claims is drawn to a nucleotide sequence of SEQ ID NO:1 or a part thereof which is active as a promoter and a nucleotide sequence of SEQ ID NO:2 or a part thereof which is active as a terminator. The present claims are drawn to undefined “parts,” *i.e.* portions or fragments, of the claimed sequences having certain activities or function. In the case of SEQ ID NO:1 the “parts” of the sequence have promoter activity; in the case of SEQ ID NO:2 the “parts” of the sequence have terminator activity. Thus, the present claims are broad genus claims that encompass a wide array of molecules.

The specification does not disclose any of the “parts,” fragments or portions of either of SEQ ID NO:1 or SEQ ID NO:2 embraced by the claims. Moreover, the specification fails to disclose any teachings as to how the structures of these sequences relate to their function. In other words, the specification fails to disclose what sequence or domains of SEQ ID NO:1 or SEQ ID NO:2 are required for a part, portion or fragment to maintain the claimed activities. Thus, the specification does not describe the complete structure of a representative number of

Art Unit: 1636

species, partial structure and relevant identifying characteristics to adequately describe the present invention. Absent teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed sequence fragments in such full, clear, concise and exact terms so as to indicate to one of skill in the art that Applicant had possession of these molecules at the time of filing of the present application.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 8-16, 21 and 22 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,

Art Unit: 1636

- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Nature of the invention and breadth of the claims

The present invention involves the construction and use of plasmid vectors for use in the expression of protein. The present claims are drawn to a nucleotide sequence of SEQ ID NO:1 or a part thereof, which is active as a promoter, and a nucleotide sequence of SEQ ID NO:2 or a part thereof which is active as a terminator. The present claims are drawn to undefined “parts,” *i.e.* portions or fragments, of the claimed sequences having certain activities or function. In the case of SEQ ID NO:1 the “parts” of the sequence have promoter activity; in the case of SEQ ID NO:2 the “parts” of the sequence have terminator activity.

Guidance provide and presence of working examples in the specification

The specification does not disclose any of the “parts,” fragments or portions of either of SEQ ID NO:1 or SEQ ID NO:2 embraced by the claims. Moreover, the specification fails to disclose any teachings as to how the structures of these sequences relate to their function. In other words, the specification fails to disclose what sequence or domains of SEQ ID NO:1 or SEQ ID NO:2 are required for a part, portion or fragment to maintain the claimed activities.

State of the prior art and unpredictability of the art

Although the state of the art is high, it would be unpredictable to make parts or fragments of the presently claimed nucleic acid sequences which maintain their desired activity as a promoter, SEQ ID NO:1 or terminator, SEQ ID NO:2. At best, one of skill in the art may be able

Art Unit: 1636

to screen for certain structural characteristics or function. Screening would not eliminate the unpredictability of false positive or negative results. For instance, one of skill in the art may make a construct comprising a part of the promoter of SEQ ID NO:1, the promoter may have no activity or may have activity at such a basal level that the screens used by one of skill in the art would not be adequate to identify the construct. Moreover, screening does not enable one of skill in the art to make or use the claimed vectors with the desired activity for each component *de novo*. It is merely a method of finding not of making. Thus, given the nature of the invention, the scope of the claims, the lack of guidance in the specification and the unpredictability of the art, it would require undue experimentation for one of skill in the art to make and use the invention claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 19 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 and 19 refer to the same deposit accession number. However, the plasmid in claim 7 is recited as pEPGsec and the *E. coli* in claim 19 is recited as pEPGseq. It is unclear whether the plasmid contained in the *E. coli* of claim 19 is the same as or different from the plasmid of claim 7 due to this inconsistency. It is also noted that the plasmids recited in claims 4-7 and the *E. coli* strains recited claims 17-20 have the same DSMZ accession numbers. This manner of identification is acceptable because it is the practice when depositing plasmids to

Art Unit: 1636

deposit them in host strains. Moreover, it is well within the ability of those of skill in the art to isolate the deposited plasmids from host strains. See e.g.

http://www.dsmz.de/download/patents/dna_engl.pdf (document requesting disclosure for deposit of plasmids including a listing of the host organism).

Claim 8 recite the phrase “foreign protein.” This phrase is vague and indefinite because it is unclear whether Applicant intends the claim to mean a heterologous protein or any protein not found in the genome of the host cell.

Claim 23 provides for the use of a DNA sequence according to SEQ ID NO:1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 23 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Allowable Subject Matter

Claims 4, 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 6 is objected for the reasons above.


Claims 17, 18 and 20 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Konstantina Katcheves
Group Art Unit 1636
18 March 2004